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1. Purpose

This document provides definitions and procedures for assigning District Office inspection conclusions and decisions to an Establishment Inspection Report (EIR) within established timeframes. This Field Management Directive (FMD) does not currently include classification of conclusions and decisions for Interstate Travel Program (ITP) inspections (under revision).

2. Background


The Field has traditionally had guidelines based on nationally established policy for the classification of EIRs published in the Regulatory Procedures Manual (RPM), the Data Codes Manual, and this FMD. With the implementation of FACTS (Field Accomplishments and Compliance Tracking System), the Data Codes Manual was no longer maintained.

3. Discussion

The classification process must be accurate, timely, and uniform since the compliance status of EIRs has broad ramifications and impacts directly on critical public health issues. The changes outlined in this FMD are modifications designed to bring greater uniformity in decisions and conclusions in conjunction with FACTS.

One of the primary differences between PODS and the current FACTS is the addition of a “Final Decision” block in FACTS. The organizational unit authorized to make the “Final Decision” is dependent on both the *types* of conclusions and decisions made, and the *program areas* involved. The requirements for “Final Decisions” are described in the procedures below.

Experienced Investigations Branch (IB) personnel are authorized to provide the “Inspection Conclusion” and “District Decisions” in FACTS for all inspection classifications (NAI, VAI, OAI, RTS, RTC). Investigational personnel are **not** authorized to check off the “Final Decision” block in FACTS except for the

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conclusions of “No Action Indicated (NAI)” and “Voluntary Action Indicated (VAI)” as *described below*.

District and Center compliance personnel may change a District Decision of OAI to VAI if they determine that none of the regulatory (advisory, administrative, or judicial) actions listed below will be taken or recommended and they are authorized to make the “Final Decision” as described in the procedures below.

Authorized District Investigations Branch staff or Compliance personnel reviewing State Contract Inspections are authorized to provide the “Final Decision” in FACTS for all inspection classifications as described in the procedures below.

4. Policy


Domestic and foreign EIRs for all programs will be classified to reflect the compliance status at the time of the inspection. The classification will reflect the “Inspection Conclusion,” “District Decision,” and the recommended advisory, administrative, or judicial action, if applicable.

EIRs should be completed and submitted for final classification within a timely manner commensurate with the current regulatory action time frames for the anticipated regulatory action, but generally not to exceed 30 working days when no further action is expected. In all cases, District time frames should be established and adhered to as closely as possible. The District Decision should be accomplished promptly after completion of the EIR.

All endorsements with “District Decisions” classified as Referred to Center (RTC), Referred to State (RTS), VAI or OAI must (1) cite or be associated with a violation(s) of a specific law, regulation, or administrative requirement, (2) identify the specific action being recommended, and (3) be supported by **documented evidence** as follows:

- FDA's jurisdiction (unless the classification is RTS and FDA cannot take action), and/or
- A summary of objectionable conditions listed on the Inspectional Observations form (FDA-483), in the EIR, and/or related documents which are cited by the District to support a specific regulatory (advisory, administrative, or judicial) recommendation or other follow-up.


In the interest of quality and efficiency, it is imperative that IB inform the Compliance Branch (CB) whenever significant objectionable conditions are observed that may warrant a regulatory action or follow-up communication. IB and CB will endeavor collectively to assure that each EIR and the subsequent “District Decision,” “Final Decision,” and recommendation are accurate, timely, uniform, and adequately documented.

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5. Inspection Conclusion

The “Inspection Conclusion” indicates IB management’s evaluation of the significance of objectionable conditions and/or practices found during the inspection. The data entry block for the “Inspection Conclusion” is located in the “Inspected Process and Conclusions” section of the FACTS “Maintain Inspection Results” screen. This section is also used to record the Program Assignment Code (PAC) and product/process covered during the inspection. If an EIR covers more than one PAC and product/process, there must be an “Inspection Conclusion” recorded for each PAC and product code. “Inspection Conclusion” definitions are listed as follows:

FACTS – “Inspection Conclusion”	DEFINITION
No Action Indicated (NAI)	No Objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further FDA action).
Correction Indicated (CI)	Objectionable conditions and practices were found during the inspection, for which the establishment failed to meet either regulatory or administrative requirements. A CI conclusion should be made only if a FDA-483 has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3. Correction may be achieved through the firm’s voluntary action or FDA action.
Referred to Center (RTC)	RTC is a temporary in-process conclusion showing that the EIR should be referred to the appropriate Center for the “Final Decision” on the “Inspection Conclusion” and “District Decision.” This conclusion should only be used when <i>there is no current policy regarding the objectionable conditions observed or significant technical issues exist which require Center review and decision.</i> A RTC classification should be made only if a FDA-483 has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3.

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6. District Decision

The “District Decision” represents the action that the District will take or recommend after considering the findings of the inspection, any events that occurred following the findings, and Agency policy. Investigation and Compliance personnel are responsible for assigning the District Decision for EIRs as outlined in the PROCEDURES section of this FMD.

The District Decision section is located in the FACTS “Maintain Inspection Results” screen below the “Inspected Process and Conclusions” section. It includes blocks to record the “Decision Type” for each PAC and “Process (Product)” covered. If an EIR covers more than one process under a specific PAC, there must be a District Decision for each process and PAC code combination.

The following District Decisions will be used as appropriate:

FACTS – “Decision Type”	DEFINITION
No Action Indicated (NAI)	No objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).
Voluntary Action Indicated (VAI)	Objectionable conditions were found and documented but the District and/or Center is not prepared to take or recommend any of the regulatory (advisory, administrative, or judicial) actions listed below since the objectionable conditions do not meet the threshold for regulatory action. The district may use an Untitled Letter, Regulatory Meeting or other communication with responsible individuals to inform the establishment of findings that should be corrected. A written response by the establishment may be an option, but is not necessary. Any corrective action is left to the establishment to take voluntarily. A VAI classification should be made only if a FDA-483 has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3. A VAI classification can be made only if the “Inspection Conclusion” is CI.


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Official Action Indicated (OAI)	Objectionable conditions were found and one of the regulatory actions listed below should be recommended. Includes inspections resulting in recalls where the district has decided conditions warrant regulatory (advisory, administrative, or judicial) action. Typically, an OAI classification should be made only if a FDA-483 has been issued and the documented evidence supports the action recommended (unless the only significant observations are non-reportable, as specified by IOM 5.2.3.3, or in matters referred to OCI, as noted in “Referred to Office of Criminal Investigations (OCI)” below). An OAI classification can be made only if the “Inspection Conclusion” is CI.
Referred to State (RTS)	Referred to State, local, or other federal office. This classification can be used only when either there is no federal jurisdiction over the apparent violation in question or it is determined that State action is the most efficient method of obtaining the establishment’s compliance with applicable Federal Laws, Regulations or Administrative requirements. An RTS classification can be made only if the “Inspection Conclusion” is CI.
Referred to Center (RTC)	This “District Decision Type” can only be used when the objectionable conditions or apparent violations noted constitute a compliance area for which <i>no clear policy has been established or significant technical issues exist</i> which require Center review and decision. An RTC classification should be made only if a FDA-483 has been issued unless the only significant observations are non-reportable as specified by IOM 5.2.3.3 and documented evidence is present to assist in the Center’s decision. An RTC classification can be made only if the “Inspection Conclusion” is either CI or RTC.

7. Procedures

A. Investigations Branch Responsibilities:

The Supervisory Investigator reviews the EIR to determine if it includes the evidence needed to draw a conclusion based on relevant policy and procedure (such as the IOM, CPGM, CPGs, and/or the RPM). If adequate evidence is present, the “Inspection Conclusion” and “District Decision” must be entered for each PAC and product covered during the inspection. The “Inspection Conclusion” and “District Decision” should be entered promptly following the completion of the official EIR. When necessary information has not been obtained, the Supervisory Investigator will take or recommend the appropriate action.

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i. “No Objectionable Conditions or Practices Found” Inspections:

If the Supervisory Investigator concludes that no objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action, an “Inspection Conclusion” of “No Action Indicated (NAI)” should be selected. The “Final Decision” block should be checked off in FACTS as noted below.

ii. “Objectionable Conditions or Practices Found” Inspections:

If the Supervisory Investigator concludes that significant, valid, and documented objectionable conditions or practices were found, the District Decision must then be one of the following:


- 1) If the significant objectionable conditions and practices were found, but the District is not prepared to take or recommend any regulatory action, the Supervisory Investigator should then assign the “District Decision Type” of “Voluntary Action Indicated (VAI)” and check off the “Final Decision” block in FACTS as noted below.

If the IB determines that an “Untitled Letter” or a Regulatory Meeting to discuss the findings is warranted, the endorsement should reflect this decision. Typically, the Supervisory Investigator should enter the “District Decision Type” of VAI, create a FACTS Compliance Assignment, and inform the Compliance Branch. Once a Compliance Assignment is initiated in FACTS, Compliance Branch is responsible for checking off the “Final Decision” block.

The Supervisory Investigator will NOT be able to link the “Inspection Record” to the Compliance Assignment upon creating the assignment; however, the Compliance Officer who receives the assignment can do so after changing the status of the assignment to “In Progress.”

- 2) If the significant objectionable conditions or practices warrant a Warning Letter or one of the other regulatory actions listed below, the Supervisory Investigator/ will assign the “District Decision Type” of “Official Action Indicated (OAI).” This would include an establishment conducting a voluntary recall where the District has decided conditions warrant regulatory action. The Supervisory Investigator will include in the EIR endorsement an evaluation of inspection findings and a recommended action and inform Compliance Branch.

When an OAI classification is entered into FACTS, the Supervisor will be prompted and should either create a new Compliance Assignment or link the inspection to an existing assignment.

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- 3) If significant objectionable conditions or practices are present but the Agency either cannot or chooses not to take regulatory action, IB may recommend that the State consider some action, assign a “District Decision” of “Referred to State (RTS)”, and notify Compliance Branch of the recommendation. Compliance Branch must be informed prior to contacting the State. Compliance Branch will assess, concur, and prepare the memorandum for referral to the State, and monitor the State’s response to the request. In the event Compliance does not concur with IB’s recommendation, they will change the “District Decision” and determine the appropriate “Final Decision.”
- 4) If the significant objectionable conditions or practices appear to warrant regulatory action, but the apparent violations noted constitute a compliance area for which no clear policy has been established or there are significant technical issues which require Center review and decision, the Supervisory Investigator/ will assign the “District Decision Type” of “Referred to Center (RTC).” The endorsement should reflect this decision and Compliance Branch must be informed prior to IB forwarding the EIR to the Center for evaluation. NOTE: Do not use “Referred to Center (RTC)” district decision for Bioresearch Monitoring inspections unless there are extraordinary circumstances. Use NAI, VAI, or OAI, as appropriate.


B. Compliance Branch Responsibilities:

When IB has determined that objectionable conditions or practices were found, that adequate evidence is present, and has made a “District Decision” of RTC, RTS, or OAI, Compliance Branch must review the EIR, endorsement, and other information provided. Compliance Branch will evaluate the IB referral and take appropriate action as required. When evidence is insufficient, Compliance Branch will develop an enforcement strategy in collaboration with IB, the Center(s), and/or ORA Headquarters as appropriate.

Compliance Branch will make the “Final Decision” in FACTS for the District except as noted in section 3. *FACTS - “Final Decision”* below. To arrive at the appropriate “final decision”, Compliance Branch may initiate further inquiries to evaluate the evidence, e.g. follow-up assignments, reference searches, consultations, regulatory meetings, etc. (See RPM for further discussion and uses of Regulatory Meetings.)

i. “Voluntary Action Indicated (VAI)” – Instructions

If IB has determined that significant objectionable conditions and practices were found, has assigned the “District Decision Type” of “Voluntary Action Indicated (VAI),” and determined that an “Untitled Letter,” a Regulatory Meeting, or other communication with the establishment to discuss the findings is warranted, the Supervisory Investigator will create a FACTS Compliance assignment and the

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Compliance Officer will link the inspection record to the assignment. If the Compliance Assignment is not created by the supervisory investigator, the Compliance Officer should create one and link the inspection record to it.

Compliance Branch will review the EIR, determine if the recommended action is appropriate, and whether adequate evidence has been provided to support the action. If Compliance Branch concurs, it will check off the “Final Decision” block, prepare the appropriate recommendation for the “Untitled Letter,” arrange a Regulatory Meeting, or otherwise communicate with the establishment in question. If Compliance Branch does not concur, it will change the “District Decision,” document the justification for the change per District procedures, check off the “Final Decision” block, and take or recommend any appropriate action.


ii. “Official Action Indicated (OAI)” – Instructions

If IB has determined that significant objectionable conditions or practices found during a domestic or foreign inspection warrant a Warning letter or one of the other regulatory actions listed below, IB will assign the “District Decision Type” of “Official Action Indicated (OAI),” and recommend an action. FACTS will automatically generate an assignment for Compliance Branch. Compliance Branch will review the EIR, determine if the recommended action is appropriate, and whether adequate evidence has been provided to support the action. If Compliance Branch concurs, it will prepare any recommendation required for Center, OCC, and HQ review per the RPM, CPGM, etc. If Compliance Branch does not concur, it will change the “District Decision,” document the justification for the change per District procedures, check off the “Final Decision” block, and take or recommend any appropriate action.

Whenever Untitled Letters or Regulatory Meetings are determined to be the appropriate action, an assessment of the firm’s response to these advisory actions should be made. If it is determined their response or proposed voluntary corrections are inadequate or require verification, a final classification or re-classification of OAI can be entered.

iii. “Referred to Center (RTC)” – Instructions

If IB has determined that the findings constitute a compliance area for which no clear policy has been established or significant technical issues exist which require Center review, and has entered the “District Decision” as “Referred to Center (RTC),” Compliance Branch will review the recommendation and determine if the referral is required. If Compliance does not concur, it will change the “District Decision,” document the justification for the change per District procedures, check off the “Final Decision” block, and take or recommend any appropriate action. If

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Compliance Branch concurs, they will inform the appropriate Center of the decision via email or memo, which shall be made part of the establishment file. These reports should be monitored to ensure that the “Inspection Conclusion,” “District Decision,” and “Final Decision” are entered into the data system under the fiscal year in which the inspection was made. NOTE: Do not use this decision for a report being forwarded to a Center for concurrence with a regulatory action being recommended by the district.

iv. “Referred to State (RTS)” – Instructions


When the Supervisory Investigator has determined significant objectionable conditions or practices are present, but the Agency either cannot or exercises discretion not to take regulatory action, IB will assign a recommended “District Decision” of “Referred to State (RTS)”. Since the reason for a referral is usually to request the State to consider some action, Compliance Branch shall review and assess the recommendation. If Compliance Branch concurs, it will prepare a memorandum for referral to the State. Compliance is obligated to maintain contact with the State to monitor action taken. If Compliance does not concur, it will change the “District Decision,” document the justification for the change per District procedures, check off the “Final Decision” block, and take or recommend any appropriate action.

C. FACTS – “Final Decision”

With the exception of instances where the compliance program reserves to a Center the right of “Final Decision” or the District has made the “District Decision” of RTC, the appropriate District unit may check off the “Final Decision” block in FACTS as follows:

IB must check off the “Final Decision” block for any inspections classified NAI or VAI, except when an Untitled Letter or a Regulatory Meeting has been recommended.

Compliance Branch must check off the “Final Decision” block for any “District Decisions” of VAI for which an Untitled Letter or a Regulatory Meeting has been recommended, OAI classifications, RTC for which the compliance program does not reserve the Final Decision for the Center, and any RTS classifications.

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REGULATORY (ADVISORY, ADMINISTRATIVE, or JUDICIAL) ACTIONS:

Application Action: e.g. {Recommendation for Denial of Pending Application (NDA, NADA, ANDA, PMA, etc.); Recommendation for Revocation of Approved Application (NDA, NADA, ANDA, PMA, etc.)}

Banning

Certification Withholding or Revocation

Citation

Civil Penalty

Demand for Destruction or other Disposition

Disqualification

Emergency Permit Disapproved

Injunction

License Action: e.g. {Denial, Suspension, or Revocation; Notice of Intent to Revoke License (for Biologics)}

Prosecution

Provisional Listing

Recall (FDA initiated recalls)

Remove from Shippers List

Seizure/Detention

Use Prohibited

Warning Letter


(See section "Compliance Branch Responsibilities" section B. above regarding classification of Untitled Letters or Regulatory Meetings as OAI)

D. Referred to Office of Criminal Investigations (OCI)

This was a designation under PODS that is no longer available in FACTS, but may be applicable. Whenever an EIR is referred to OCI for further investigative follow-up or as part of an OCI case, the report should be classified as "OAI".

E. Follow-up Classifications to OAI EIRs

An OAI classification indicates that an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health. It also may delay an establishment seeking government contracts or approvals. Therefore, an appropriate and timely follow-up inspection is encouraged to ensure compliance and corrections to violations at an establishment that has an OAI inspection classification at the most recent inspection. It is recommended that these follow-up inspections be conducted within six months after an OAI classification. However, there may be circumstances when a follow-up inspection may be conducted in less than six months after an OAI classification, such as when a significant hazard to health exists and/or when the Agency may be contemplating an enforcement action. There may also be instances when the follow-up inspection will be conducted greater than six months after the OAI inspection, such as when the firm is actively engaged with the district office regarding corrective actions that require a greater

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length of time to implement. If the previous inspection was OAI and the re-inspection or verified corrective action is either VAI or NAI, the new classification must be reported in FACTS promptly but not to exceed ten working days from the completion of the inspection.

8. Inspections Conducted by State Personnel

Assignment of uniform classifications to state inspections performed under FDA contracts or agreements are essential to the success of these programs. State officials responsible for submitting EIRs to FDA are to be furnished with copies of this FMD and instructed in the use of these criteria. Copies of any other pertinent guidelines and programs shall be furnished.

Do not consider violations of state law or regulations, that are not actionable under current FDA policy, in reaching conclusions or decisions on EIRs. These violations should be pursued under the state programs.

Classification of Violative State Contract Inspection Reports

FDA Districts are responsible to review and assess State Contract Inspection Reports to determine the appropriate classification and enter a final District Decision in FACTS. Classification of state conducted inspections should follow the same guidance as for FDA conducted inspections.

When classifying a violative State contract inspection report, a final "District Decision" of Official Action Indicated (OAI) shall be used when it is determined that further action or follow up by FDA is necessary. In this case, Investigations Branch management, in consultation with Compliance Branch and/or the State Contract Agency, if necessary, will decide the appropriate course of action such as a follow-up inspection and collecting compliance samples.


If the reviewing Supervisory Investigator determines that follow up by the contracting state is the appropriate action, the report shall be classified as follows:

- Inspection Conclusion: Correction Indicated (CI)
- District Decision: Referred To State (RTS)

The District is responsible to follow up with the State Contract Agency to verify that the violations were corrected or that appropriate regulatory follow up is taken when appropriate.

Other Instructions:

Whenever an establishment assigned to be inspected is determined to be out of business (OOB), or no inspection was made since the firm is not FDA regulated, seasonal operations only, or inactive, no "Inspection Conclusions," and "District Decisions" or other inspection data should be entered for this assignment. The

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preferred method for capturing time for work associated with the inspection assignment is to convert the assignment from an operation (12) "Inspection" to an operation (13) "Investigation". This is accomplished in FACTS by first changing the "Operational Status" of the establishment in the "Maintain Firms" to the appropriate designation: Out of Business (OOB), Not Official Establishment Inventory (NOE), Seasonal (SEA), or Inactive (INA). The "Lead Investigator" should then update the assignment in their inbox by changing the assignment operation code from (12) to (13). For further information contact your District's FACTS coordinator.

9. References/Supporting Documents

- 1) [Investigations Operations Manual](#)
- 2) [Regulatory Procedures Manual](#)
- 3) [Compliance Program Guidance Manual](#)
- 4) [Compliance Policy Guides](#)

FMD Document History/Change History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
3.0	R	29 DEC. 2011	DAVID GLASGOW, DIRECTOR, DDFI	David Elder, Director, ORO

- D: Draft, I: Initial, R: Revision, C: Cancel

Version 3: Provided the determination of appropriate classification, the follow-up with State Contract Agency to verify violations or appropriate regulatory follow-up is taken, and the authorization to insert "Final Decision" in FACTS to the District's IB or Compliance staff for State Contract Inspections; Added OAI follow-up inspection recommended timeframes.